PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Melatonin NET 1 mg/ml oral solution (Melatonin)

This is a summary of the risk management plan (RMP) for Melatonin NET 1 mg/ml oral solution (hereby referred to as Melatonin). The RMP details important risks of Melatonin and how these risks can be minimised, and how more information will be obtained about Melatonin's risks and uncertainties (missing information).
Melatonin's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Melatonin should be used.

Important new concerns or changes to the current ones will be included in updates of melatonin's RMP.

I. The Medicine and What it is Used For

Melatonin is indicated for
- Short-term treatment of jet lag in adults.
- Insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient.

It contains melatonin as active substance and to be taken by oral route of administration.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks when taking Melatonin, together with measures to minimise such risks, are outlined below.
Measures to minimise the risks identified for medicinal products can be:
- Specific information such as warnings, precautions, and advice on correct use in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.
In addition to these measures, information about adverse reactions is collected continuously and is regularly analysed so that immediate action can be taken when necessary. These measures constitute routine pharmacovigilance activities.

II.A List of Important Risks and Missing Information

Important risks of Melatonin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential risks. Identified risks are concerns for which there is sufficient proof that links them with the use of Melatonin. Potential risks are concerns for which an association with the use of this medicine is possible based on available

data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected.

List of Important Risks and Missing Information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of Important Risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation, or specific obligations of Melatonin.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Melatonin.